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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,591

08/19/2003

Takaaki Isshiki

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EXAMINER

OU, JING RUI

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

12/22/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/642,591	Applicant(s) ISSHIKI ET AL.	
	Examiner JING OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the amendment filed along with the RCE filed on 09/15/2009. Claims 1 and 3-11 are pending. Claim 1 is independent. Claim 2 is cancelled. Claims 10 and 11 are newly added.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/15/2009 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation "wherein the flexible shaft always serves as the guide wire for the balloon catheter" in Claim 11 does not have sufficient support in the original disclosure.

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5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how the flexible shaft always serves as a guide wire for the balloon catheter. The flexible shaft does not always serve as the guide wire for the balloon catheter. It also at least serves as a guide wire/shaft for the thrombus capture member.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 3, 4, 7, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116).

Khosravi discloses a sheath (the portion of sheath 52 which has the enlarged distal region of lumen 64 as described in col. 5, lines 19-22) being closed at the proximal end (by the narrow proximal region described in col. 5, lines 19-25), a flexible shaft (the combination of shaft 12 and member 54 which is attached thereto as indicated in col. 5, lines 32-35, and noting that shaft 12 is flexible in the embodiment described in col. 4, lines 13-16 due to the articulations therein), the flexible shaft being a wire member (Shaft 12 and attached member 54 together are a "wire" member since this member is very thin, as indicated in col. 5, lines 39-42, and elongated. The fact that the member has a passageway does not preclude the member from being a wire. For example, some guide wires have an elongated passageway through them for fluid delivery. Yet, they are wires.), thrombus capture member 14, 16 comprising a plurality of wires 24 forming a frame and having a configuration swollen in the middle portion and mounted slidably on shaft 12 at the distal end but fixed on the shaft at the proximal end thereof (col. 4, lines 24-27). Khosravi fails to disclose the filter frame wires 24 comprising a plurality of spirally-configured wires. However, Brooks et al. teach that

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filter frame wires 56 comprising a plurality of spirally-configured wires (Fig. 4), said wires being arranged around a shaft by surrounding the shaft spirally and by allowing the wires to cross each other (Fig. 4 and col. 4, lines 37-43) apparently in order to obtain the advantage of better supporting the filter membrane around its circumference. It would have been obvious to make the Khosravi filter frame wires 24 spiral and crossed with one another so that it too would have this advantage. As to claim 4, Khosravi fails to disclose a hemostatic valve and a tubular member to hold it. However, it is old and well known to use hemostatic valves and tubular members to hold the valves in surgical devices in order to obtain the advantage of preventing blood loss. It would have been obvious to include a hemostatic valve and tubular member in the Khosravi device so that it too would have this advantage. The proximal portion of shaft 12 of Khosravi protrudes from the sheath 52 when the shaft 12 is inserted therein as described in col. 5, lines 51-56. As to claim 7, Khosravi fails to disclose the slide ring assembly as comprising an inner ring and an outer ring with the wires sandwiched therebetween. However, it is old and well known in this art to secure wires between inner and outer rings in order to obtain the advantage of providing a strong attachment between the wires and ring assembly. It would have been obvious to so construct the sliding ring in the Khosravi device so that it too would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

11. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116) as applied to claim 1 above,

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and further in view of Rosenbluth (WO 99/56801). As to claim 5, Khosravi fails to disclose a side hole and second lumen in the sheath. However, Rosenbluth teaches that a sheath 11 for an intravascular filter should include a side hole 310 and second lumen 309 in order to obtain the advantage of permitting rapid exchange of the sheath (page 18, lines 13-22). It would have been obvious to include a side hole and second lumen in the Khosravi sheath so that it too would have this advantage. As to claim 6, Khosravi fails to disclose a side infusion tube. However, Rosenbluth teaches that a sheath 11 for an intravascular filter should include a side infusion port 15 attached thereto in order to obtain the advantage of permitting injection of contrast medium into the vessel (page 15, lines 15-24). It would have been obvious to include a side infusion port in the Khosravi device so that it too would have this advantage.

12. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116) as applied to claim 1 above, and further in view of Boylan et al (US Pat. No.: 6,602,272).

As to claims 9 and 10, Khosravi in view of Brooks et al discloses all the limitations of the claim as taught above and further discloses that the filter is a funnel-shaped member including a constricting part and a constricted part extending from the smaller end of the constricting part, said constricting part being provided with plural pores and that the thrombus capture member is slidably attached the distal end thereof to the shaft by a slide ring and fixed at the proximal end thereof to the shaft by a fixed ring (col. 4, lines 24-27 and Fig. 1-2B). Khosravi in view of Brooks et al does not appear to disclose a cylindrical part. However, Boylan et al teaches a filter comprising a

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cylindrical part. The motivation/suggestion for doing so would have been served as a superstructure to which the filter and the struts of the strut assembly can be adhesively or otherwise affixed (Col. 5, lines 51-53). In addition, the cylindrical part provides better attachment of the filter to the blood vessel since more surface area of the filter contacts the blood vessel wall. Therefore, it would have been obvious to combine Boylan et al with Khosravi and Brooks et al to obtain the claimed invention as specified in the instant claim.

Response to Arguments

13. Applicant's arguments filed 09/15/2009 have been fully considered but they are not persuasive.

Shaft 12 and attached member 54 together are a "wire" member since this member is very thin, as indicated in col. 5, lines 39-42, and elongated. The combination of shaft 12 and attached member 54 functions as a guide wire for the distal end of the thrombus capture member to slide on the shaft 12. In addition, the combination of shaft 12 and attached member 54 functions as a guide wire to guide the thrombus capture member to slide along the wire 68.

The combination of Khosravi and Brooks et al is to modify filter frame wires of the thrombus capture member of Khosravi to comprise a plurality of spirally-configured wires in order to obtain the advantage of better supporting the filter membrane around its circumference as taught by Brooks et al. The combination is not for modifying the ends of the thrombus capture member of Khosravi. Khosravi clearly discloses that one

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end of the thrombus capture member is being fixed on the shaft 12 and the other end is being slidable on the shaft 12 (col. 4, lines 17-27).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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